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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,655	09/16/2005	Tetsuya Sakata	10921.354USWO	7657
52835 7590 02/15/2011 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902				
EXAMINER SIMPSON, SARAH A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,655

Applicant(s)

SAKATA ET AL.

Examiner

SARAH A. SIMPSON

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-942)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/2010 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 17 and 25** are rejected under 35 U.S.C. 102(b) as being anticipated by **Mauze et al. (US 6,210,420)**.

Regarding claims 1, 17 and 25, Mauze discloses a lancing device comprising: a needle (124 or 194); a moving member (128 or 178) for moving the needle in an advancing direction from a standby position to a puncturing position, the needle being attached to the moving member (figs. 1, 7-8); and a housing (106,104 or 172, 174) arranged to allow the moving member to move in the advancing direction and in a

retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (156 or 184,190) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (fig. 1 or 202) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 4, lines 25-41; columns 5-6, lines 66-67, 1-22). Mauze also discloses a dividing wall (179) for dividing the first inner space (184, 190) of the housing and the second space ((202); figs. 7-8); wherein the dividing wall (179) is connected between the moving member (178) and the housing ((172, 174); figs. 7, 8).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. **Claims 1-4 and 6-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sato et al. (US 7,131,984 B2)** in view of **Mauze et al. (US 6,210,420)**.

Regarding claims 1 and 23, Sato et al. disclose a lancing device comprising: a moving member (31) for moving a needle in an advancing direction from a standby position to a puncturing position; and a housing (2) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (30) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (21) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 7, lines 4-22). Sato et al. disclose a latch (15) for holding the moving member at the standby position (fig. 1).

Sato et al. fail to disclose wherein the needle is attached to the moving member.

However, Mauze teaches a lancing device comprising: a needle (124 or 194); a moving member (128 or 178) for moving the needle in an advancing direction from a standby position to a puncturing position, the needle being attached to the moving member (figs. 1, 7-8); and a housing (106,104 or 172) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the

housing, wherein the housing includes a first space (156 or 184,190) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (fig. 1 or 202) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 4, lines 25-41; columns 5-6, lines 66-67, 1-22). Mauze also discloses a dividing wall (179) for dividing the first inner space (184, 190) of the housing and the second space ((202); figs. 7-8); wherein the dividing wall (179) is connected between the moving member (178) and the housing ((172, 174); figs. 7, 8).

Given the teachings of Mauze, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sato et al. with the moving member and the needle attached to one another. Doing so would reduce the overall size of the lancet device, making it more convenient to handle.

Regarding claim 2, Sato et al. essentially disclose the lancing device according to claim 1, further comprising a fixing means (31a) for fixing the moving member to the housing at the standby position, with an urging force applied in the advancing direction, and also comprising a disengaging means (4) for dissolving the fixing of the moving member, wherein the moving member is moved from the standby position in the advancing direction by the urging force (column 6, lines 56-61).

Regarding claim 3, Sato et al. essentially disclose the lancing device according to claim 2, wherein the urging force is applied to the moving member by a resilient member ((34); columns 6-7, lines 62-67, 1-3).

Regarding claim 4, Sato et al. essentially disclose the lancing device according to claim 3, wherein the resilient member is a coil spring (34, 17a, 17b) or a bellows (column 7, lines 66-67).

Regarding claim 5, Sato et al. essentially disclose the lancing device according to claim 1, wherein the pressure difference causes the moving member to receive suction directed in the retreating direction (abstract).

Regarding claim 6, Sato et al. essentially disclose the lancing device according to claim 5, wherein the moving member (31) is moved in the retreating direction (N2) by making pressure in the first space (30) smaller than pressure in the second space (21) beyond a predetermined value (column 8, lines 53-60).

Regarding claim 7, Sato et al. essentially disclose the lancing device according to claim 6, wherein the moving member is moved in the retreating direction by making pressure in the first space smaller than atmospheric pressure beyond a predetermined value (column 9, lines 6-16).

Regarding claim 8, Sato et al. essentially disclose the lancing device according to claim 5, further comprising a negative pressure generating means for generating a negative pressure in the second space (column 9, lines 6-16).

Regarding claim 9, Sato et al. essentially disclose the lancing device according to claim 8, wherein the negative pressure generating means individually generates

negative pressure in the first space and the second space (columns 8-9, lines 53-67, 1-16).

Regarding claim 10, Sato et al. essentially disclose the lancing device according to claim 8, wherein the negative pressure generating means generates the negative pressure in the first space for applying a suctioning force to the moving member, so that the moving member is moved to the standby position (columns 8-9, lines 53-67, 1-16).

Regarding claim 11, Sato et al. essentially disclose the lancing device according to claim 8, wherein the negative pressure generating means comprises a pump (3).

Regarding claim 12, Sato et al. essentially disclose the lancing device according to claim 2, wherein air flow into the first space (30) is caused before or on disengaging the moving member (31) by the disengaging means ((4); column 8, lines 54-64).

Regarding claim 13, Sato et al. essentially disclose the lancing device according to claim 12, wherein the air flow into the first space is caused when the moving member is disengaged by the disengaging means (column 8, lines 54-64).

Regarding claim 14, Sato et al. essentially disclose the lancing device according to claim 13, wherein the disengaging means (4) comprises an operating portion (5) to be operated to cause the disengaging means to act on the engaging means, wherein positional selection of the operating portion determines whether the first space (30) is caused to communicate with outside or not to communicate with the outside (column 9, lines 30-37).

Regarding claim 15, Sato et al. essentially disclose the lancing device according to claim 14, wherein the operating portion (5) is movable in the advancing direction and

the retreating direction, with part thereof protruding out of the housing, the operating portion including an engaging part (52) accommodated in the housing, wherein the housing is formed with a through-hole (55) for allowing the operating portion to move in the advancing direction and in the retreating direction, wherein the engaging part is used to select between a state in which the engaging part closes the through-hole and a state in which the engaging part does not close the through-hole (column 8, lines 20-24).

Regarding claim 16, Sato et al. essentially disclose the lancing device according to claim 1, wherein the second space (21) is provided with a retreating means (13) for moving the needle back in the retreating direction after the needle is brought to the puncturing position (column 7, lines 23-41; fig. 1).

Regarding claims 17, 24 and 25, Sato et al. disclose a lancing device comprising: a moving member (31) for moving a needle (10b) in an advancing direction from a standby position to a puncturing position; and a housing (2) allowing the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction, wherein a dividing wall is provided for dividing an inner space of the housing into a first space (30) offset in the retreating direction and a second space (21) offset in the advancing direction (column 7, lines 65-67; wherein a bellow is defined by a dividing wall and the spring may be replaced with a bellow), wherein the moving member (31) is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space

(abstract; columns 8-9, lines 53-67, 1-16). Sato et al. disclose a latch (15) for holding the moving member at the standby position (fig. 1).

Sato et al. fail to disclose wherein the needle is attached to the moving member.

However, Mauze teaches a lancing device comprising: a needle (124 or 194); a moving member (128 or 178) for moving the needle in an advancing direction from a standby position to a puncturing position, the needle being attached to the moving member (figs. 1, 7-8); and a housing (106,104 or 172) arranged to allow the moving member to move in the advancing direction and in a retreating direction opposite to the advancing direction; wherein the moving member moves in close contact with the housing, wherein the housing includes a first space (156 or 184,190) which is offset in the retreating direction from a portion contacting with the moving member, and a second space (fig. 1 or 202) which is offset in the advancing direction from the portion contacting with the moving member; wherein the moving member is moved in the retreating direction to be brought to the standby position by a pressure difference produced between the first space and the second space (column 4, lines 25-41; columns 5-6, lines 66-67, 1-22). Mauze also discloses a dividing wall (179) for dividing the first inner space (184, 190) of the housing and the second space ((202); figs. 7-8); wherein the dividing wall (179) is connected between the moving member (178) and the housing ((172, 174); figs. 7, 8).

Given the teachings of Mauze, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Sato et al. with the moving

member and the needle attached to one another. Doing so would reduce the overall size of the lancet device, making it more convenient to handle.

Regarding claim 18, Sato et al. essentially disclose the lancing device according to claim 17, wherein the dividing wall includes a bellows (column 7, lines 65-67).

Regarding claim 19, Sato et al. essentially disclose the lancing device according to claim 18, further comprising a fixing means (31a) for fixing the moving member (31) to the housing (2) at the standby position, with an urging force applied in the advancing direction, wherein the moving member is moved from the standby position in the advancing direction by the urging force (column 6, lines 56-61).

Regarding claim 20, Sato et al. essentially disclose the lancing device according to claim 19, wherein the urging force is applied to the moving member by at least one resilient member (34, 17a, 17b).

Regarding claim 21, Sato et al. essentially disclose the lancing device according to claim 20, wherein said at least one resilient member comprises the bellows (column 7, lines 65-67).

Regarding claim 22, Sato et al. essentially disclose the lancing device according to claim 21, wherein said at least one resilient member further comprises a coil spring ((34, 17a, 17b); column 7, lines 65-67).

Response to Arguments

Applicant's arguments filed with respect to Mauze have been fully considered but they are not persuasive. The applicant argues that Mauze teaches that the backward

movement of piston 178 is caused by a restoring force of a resilient support 204, rather than a pressure difference. The applicant cites column 6, lines 20-22 of Mauze for support of this allegation, which state, "The suction source provides the driving force for driving the lancet 194, as well as providing the reduced environmental pressure on the tissue to increase blood flow and bleeding. The removal of the suction restores the piston 178 to its original position of Fig. 7". No where can it be found that the resilient support 204 causes retraction of the lancet. Instead, Mauze clearly states that the removal of suction causes retraction of piston 178 and lancet 194. The removal of suction immediately causes a pressure different between first space 190 and second space 184. As the vacuum is stopped, air is allowed to flow back into port 180 and second space 184, increasing its pressure within. Because the air then has to pass through the thin passage 181 before it reaches the first space 190, there is an immediate pressure difference between the two chambers. It is this pressure difference that causes the piston 178 to retract. Further, claim 12 recites, the apparatus "further comprising a resilient support for *allowing* the piston to be pulled forward by reduction in air pressure at the head and retracting the piston when the reduction in air pressure is removed". In other words, the resilient member 204 provides the device with the capability of advancing and retracting, but is not the cause of it. Instead, it is the pressure difference between the two chambers controlled by the vacuum source that causes retreating of the lancet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/
Examiner, Art Unit 3731
2/10/2010

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3776